



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 878

[Docket No. FDA-2018-N-1913]

Medical Devices; General and Plastic Surgery Devices; Classification of the General

Laparoscopic Power Morcellation Containment System

AGENCY: Food and Drug Administration, HHS.

ACTION: Final amendment; final order.

SUMMARY: The Food and Drug Administration (FDA or we) is classifying the general laparoscopic power morcellation containment system into class II (special controls). The special controls that apply to the device type are identified in this order and will be part of the codified language for the general laparoscopic power morcellation containment system's classification. We are taking this action because we have determined that classifying the device into class II (special controls) will provide a reasonable assurance of safety and effectiveness of the device. We believe this action will also enhance patients' access to beneficial innovative devices.

DATES: This order is effective [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. The classification was applicable on December 19, 2017.

FOR FURTHER INFORMATION CONTACT: Cal Rabang, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4633, Silver Spring, MD, 20993-0002, 301-796-6412, Cal.Rabang@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Upon request, FDA has classified the general laparoscopic power morcellation containment system as class II (special controls), which we have determined will provide a reasonable assurance of safety and effectiveness. In addition, we believe this action will enhance

patients' access to beneficial innovation, in part by placing the device into a lower device class than the automatic class III assignment.

The automatic assignment of class III occurs by operation of law and without any action by FDA, regardless of the level of risk posed by the new device. Any device that was not in commercial distribution before May 28, 1976, is automatically classified as, and remains within, class III and requires premarket approval unless and until FDA takes an action to classify or reclassify the device (see 21 U.S.C. 360c(f)(1)). We refer to these devices as “postamendments devices” because they were not in commercial distribution prior to the date of enactment of the Medical Device Amendments of 1976, which amended the Federal Food, Drug, and Cosmetic Act (FD&C Act).

FDA may take a variety of actions in appropriate circumstances to classify or reclassify a device into class I or II. We may issue an order finding a new device to be substantially equivalent under section 513(i) of the FD&C Act (21 U.S.C. 360c(i)) to a predicate device that does not require premarket approval. We determine whether a new device is substantially equivalent to a predicate device by means of the procedures for premarket notification under section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and part 807 (21 CFR part 807).

FDA may also classify a device through “De Novo” classification, a common name for the process authorized under section 513(f)(2) of the FD&C Act. Section 207 of the Food and Drug Administration Modernization Act of 1997 established the first procedure for De Novo classification (Pub. L. 105-115). Section 607 of the Food and Drug Administration Safety and Innovation Act modified the De Novo application process by adding a second procedure (Pub. L. 112-144). A device sponsor may utilize either procedure for De Novo classification.

Under the first procedure, the person submits a 510(k) for a device that has not previously been classified. After receiving an order from FDA classifying the device into class III under section 513(f)(1) of the FD&C Act, the person then requests a classification under section 513(f)(2).

Under the second procedure, rather than first submitting a 510(k) and then a request for classification, if the person determines that there is no legally marketed device upon which to base a determination of substantial equivalence, that person requests a classification under section 513(f)(2) of the FD&C Act.

Under either procedure for De Novo classification, FDA is required to classify the device by written order within 120 days. The classification will be according to the criteria under section 513(a)(1) of the FD&C Act. Although the device was automatically placed within class III, the De Novo classification is considered to be the initial classification of the device.

When FDA classifies a device into class I or II via the De Novo process, the device can serve as a predicate for future devices of that type, including for 510(k)s (see section 513(f)(2)(B)(i) of the FD&C Act). As a result, other device sponsors do not have to submit a De Novo request or premarket approval application to market a substantially equivalent device (see section 513(i) of the FD&C Act, defining “substantial equivalence”). Instead, sponsors can use the less-burdensome 510(k) process, when necessary, to market their device.

II. De Novo Classification

On September 29, 2017, FDA received Advanced Surgical Concepts Ltd.’s request for De Novo classification of the ContainOR. FDA reviewed the request in order to classify the device under the criteria for classification set forth in section 513(a)(1) of the FD&C Act.

We classify devices into class II if general controls by themselves are insufficient to provide reasonable assurance of safety and effectiveness, but there is sufficient information to establish special controls that, in combination with the general controls, provide reasonable assurance of the safety and effectiveness of the device for its intended use (see section 513(a)(1)(B) of the FD&C Act). After review of the information submitted in the request, we determined that the device can be classified into class II with the establishment of special controls. FDA has determined that these special controls, in addition to the general controls, will provide reasonable assurance of the safety and effectiveness of the device.

Therefore, on December 19, 2017, FDA issued an order to the requester classifying the device into class II. In this final order, FDA is codifying the classification of the device by adding 21 CFR 878.4825.¹ We have named the generic type of device general laparoscopic power morcellation containment system, and it is identified as a prescription device consisting of an instrument port and tissue containment method that creates a working space allowing for direct visualization during a power morcellation procedure following a laparoscopic procedure for the excision of benign tissue that is not suspected to contain malignancy.

FDA has identified the following risks to health associated specifically with this type of device and the measures required to mitigate these risks in table 1.

Table 1.--General Laparoscopic Power Morcellation Containment System Risks and Mitigation Measures

Identified Risks	Mitigation Measures
Adverse tissue reaction	Biocompatibility evaluation
Infection	Sterilization validation, Shelf life testing, and Labeling
Intraperitoneal tissue dissemination <ul style="list-style-type: none"> • Material permeability • Improper function of containment device • Inadequate material strength • Physical trauma to liner caused by contact with morcellator or grasper/tenaculum • Damage to liner (intentional or accidental) from instrument inserted through secondary port • Tearing during removal with loss of contents into abdominal cavity • Tearing of the bag due to stones contained in tissue • Use error 	Non-clinical performance testing, Animal performance testing, Shelf life testing, Labeling, and Training
Traumatic injury to non-target tissue/organ <ul style="list-style-type: none"> • Active end of morcellator or grasper/tenaculum breaches liner • Loss of insufflation • Inadequate space to perform morcellation 	Non-clinical performance testing, Animal performance testing, Labeling, and Training

¹ FDA notes that the “ACTION” caption for this final order is styled as “Final amendment; final order,” rather than “Final order.” Beginning in December 2019, this editorial change was made to indicate that the document “amends” the Code of Federal Regulations. The change was made in accordance with the Office of Federal Register’s (OFR) interpretations of the Federal Register Act (44 U.S.C. chapter 15), its implementing regulations (1 CFR 5.9 and parts 21 and 22), and the Document Drafting Handbook.

<ul style="list-style-type: none"> • Inadequate visualization of the laparoscopic instruments and tissue specimen relative to the external viscera • Use error 	
Hernia through abdominal wall incision	Labeling and Training
Prolongation of procedure and exposure to anesthesia	Labeling and Training

FDA has determined that special controls, in combination with the general controls, address these risks to health and provide reasonable assurance of safety and effectiveness. For a device to fall within this classification, and thus avoid automatic classification in class III, it would have to comply with the special controls named in this final order. The necessary special controls appear in the regulation codified by this order. We encourage sponsors to consult with us if they wish to use a non-animal testing method they believe is suitable, adequate, validated, and feasible. We will consider if such an alternative method could be assessed for equivalency to an animal test method. This device is subject to premarket notification requirements under section 510(k) of the FD&C Act.

At the time of classification, general laparoscopic power morcellation containment systems are for prescription use only. Prescription devices are exempt from the requirement for adequate directions for use for the layperson under section 502(f)(1) of the FD&C Act (21 U.S.C. 352(f)(1)) and 21 CFR 801.5, as long as the conditions of 21 CFR 801.109 are met.

III. Analysis of Environmental Impact

The Agency has determined under 21 CFR 25.34(b) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

IV. Paperwork Reduction Act of 1995

This final order establishes special controls that refer to previously approved collections of information found in other FDA regulations and guidance. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork

Reduction Act of 1995 (44 U.S.C. 3501-3521). The collections of information in the guidance document “De Novo Classification Process (Evaluation of Automatic Class III Designation)” have been approved under OMB control number 0910-0844; the collections of information in 21 CFR part 814, subparts A through E, regarding premarket approval, have been approved under OMB control number 0910-0231; the collections of information in part 807, subpart E, regarding premarket notification submissions, have been approved under OMB control number 0910-0120; the collections of information in 21 CFR part 820, regarding quality system regulations, have been approved under OMB control number 0910-0073; and the collections of information in 21 CFR part 801, regarding labeling, have been approved under OMB control number 0910-0485.

List of Subjects in 21 CFR Part 878

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act, and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 878 is amended as follows:

PART 878--GENERAL AND PLASTIC SURGERY DEVICES

1. The authority citation for part 878 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 360l, 371.

2. Add § 878.4825 to subpart E to read as follows:

§ 878.4825 General laparoscopic power morcellation containment system.

(a) *Identification.* A general laparoscopic power morcellation containment system is a prescription device consisting of an instrument port and tissue containment method that creates a working space allowing for direct visualization during a power morcellation procedure following a laparoscopic procedure for the excision of benign tissue that is not suspected to contain malignancy.

(b) *Classification.* Class II (special controls). The special controls for this device are:

(1) The patient-contacting components of the device must be demonstrated to be biocompatible.

(2) Performance testing must demonstrate the sterility of patient-contacting components of the device.

(3) Performance data must support the shelf life of the device by demonstrating continued sterility, package integrity, and device functionality over the intended shelf life.

(4) Non-clinical performance data must demonstrate that the device performs as intended under anticipated conditions of use. The following performance characteristics must be tested:

(i) Demonstration of the device impermeability to tissue, cells, and fluids;

(ii) Demonstration that the device allows for the insertion/withdrawal of laparoscopic instruments while maintaining pneumoperitoneum;

(iii) Demonstration that the containment system provides adequate space to perform morcellation and adequate visualization of the laparoscopic instruments and tissue specimen relative to the external viscera;

(iv) Demonstration that compatible laparoscopic instruments and morcellators do not compromise the integrity of the containment system; and

(v) Demonstration that users can adequately deploy the device, morcellate a specimen without compromising the integrity of the device, and remove the device without spillage of contents.

(5) Training must be developed and validated to ensure users can follow the instructions for use.

(6) Labeling must include:

(i) A contraindication for use in gynecological procedures;

(ii) A contraindication against use of tissue that is known or suspected to contain malignancy;

(iii) The following boxed warning: “Warning: Information regarding the potential risks of a procedure with this device should be shared with patients. The use of laparoscopic power

morcellators may spread cancer. The use of this containment system has not been clinically demonstrated to reduce this risk;”

(iv) A statement limiting use of device to physicians who have completed the training program; and

(v) A shelf life.

Dated: November 17, 2021.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2021-25585 Filed: 11/22/2021 8:45 am; Publication Date: 11/23/2021]